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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0236]

Draft "Guidance for Industry: Revised Recommendations for Donor and Product Management Based on Screening Tests for Syphilis;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Revised Recommendations for Donor and Product Management Based on Screening Tests for Syphilis" dated June 2003. The draft guidance document provides recommendations for testing donors of blood and blood components for syphilis, and for recommended actions based on those test results. The recommendations described in the document are for blood establishments that use either nontreponemal-based or treponemal-based screening assays to test donors for serological evidence of syphilis infection. These recommendations, when finalized, will replace previous recommendations contained in a Memorandum to Registered Blood Establishments dated December 12, 1991.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 90 days after date of publication the* **Federal Register**], to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–cb026

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40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Joseph L. Okrasinski, Jr., Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Guidance for Industry: Revised Recommendations for Donor and Product Management Based on Screening Tests for Syphilis" dated June 2003. The draft guidance document provides specific recommendations for donor testing and management, and product disposition when using screening tests for syphilis. The recommendations are for blood establishments that use either nontreponemal-based or treponemal-based screening assays for serological evidence of syphilis infection. These recommendations, when finalized, will replace the previous recommendations contained in a Memorandum to Registered Blood Establishments dated December 12, 1991.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance document represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit written or electronic comments to ensure adequate consideration in preparation of the final guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either http://www.fda.gov/cber/guidelines.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: 6/18/03
June 18, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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